

## Message Text

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PAGE 01 STATE 196957  
ORIGIN HEW-06

INFO OCT-01 EUR-12 NEA-10 ISO-00 OES-07 MED-03 PA-02  
PRS-01 USIA-15 /057 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:PFF  
APPROVED BY OES/APT/BMP:ACHAPMAN  
DHEW/OIH: RBUHRICH  
NEA/INS:ATHIBAUT (INFO  
OES/APT/BMP:CRAWFORD(INFO)

-----092017 190109Z /61

P 182128Z AUG 77  
FM SECSTATE WASHDC  
TO AMEMBASSY VIENNA PRIORITY  
AMEMBASSY BRUSSELS  
AMEMBASSY PARIS  
AMEMBASSY BONN  
AMEMBASSY ATHENS  
AMEMBASSY NEW DELHI  
INFO AMEMBASSY ROME PRIORITY  
AMEMBASSY MADRID

UNCLAS STATE 196957

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, AU, BE, FR, GW, GR, IN,

IT, IR, JA, RP, PO, SN, SP, NS  
SUBJ CT:;PREM TUR BAXTERY DEPLETION CARDIAC PACEMAKERS  
(RECALL T-137/138-71)  
1. FDA ADVISES OF THE FOLLOWING MEDICAL DEVICE ADVISORY  
(RECALL):

PRODUCT INVOLVED:

A. T-137-7: STARR-EDWARDS VENTRAC IMPLANTABLE PACEMAKER,  
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PAGE 02 STATE 196957

MODEL NO. 8114. PACEMAKER CONTAINS A MALLORY MERCURY-ZINC  
BATTERY FROM LOT NO. 3051.

B. T-138-7: STARR-EDWARDS VENTRAC IMPLANTABLE PACEMAKER,  
MODEL NO. 8116. PACEMAKER CONTAINS A MALLORY MERCURY-ZINC  
BATTERY FROM LOT NO. 3051.

PRODUCT IDENTIFICATION:

A. T-137-7: PRODUCT LABELED IN PART: "STARR-EDWARDS 8114  
VENTRAC VENTRICULAR TRACKING (STANDBY) S/N XXXRATEXXX  
EDWARDS LABORATORIES DIVISION OF AMERICAN HOSPITAL SUPPLY  
CORP. 17221 RED HILL AVE, SANTA ANA CA. 92705 USA XXX"

B. T-138-7: PRODUCT LABELED IN PART: "MODEL 8116 IMPLANT-  
ABLE VENTRICULAR INHIBITED PULSE GENERATOR XXX MERCURY  
BATTERY POWERED UNIPOLAR TRACKING PULSE S-STYLE CONNECTOR  
XXX SERIAL NO. XXX EDWARDS PACEMAKER SYSTEMS DIVISION OF  
AMERICAN HOSPITAL SUPPLY CORPORATION P.O. BOX 19554, 1923  
S.E. MAIN STREET, IRVINE, CA. 92713XXX"

MANUFACTURER/RECALLING FIRM: EDWARDS PACEMAKER SYSTEMS,  
DIV. OF AMERICAN HOSPITAL SUPPLY CORP., 1923 S.E. MAIN  
STREET, IRVINE, CA. 92714.

2. REASON FOR RECALL: MODELS 8114 AND 8116 PACEMAKERS  
THAT USED MALLORY BATTERIES FROM CELL LOT NO. 3051 SHOW A  
HIGHER THAN USUAL PREMATURE DEPLETION RATE THAT BECOMES  
EVIDENT AT ABOUT 18-20 MONTHS AFTER IMPLANTATION. TWENTY  
NINE PACER FAILURES HAVE BEEN DOCUMENTED WITH ELEVEN MORE  
POSSIBLE FAILURES. THERE ARE NO INJURIES OR DEATHS RE-  
LATED TO THE RECALL.

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PAGE 03 STATE 196957

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO  
ASCERTAIN WHETHER THEY HAVE BEEN INFORMED OF PACEMAKER  
PROBLEM AND RECALL LETTER(S) ISSUED BY FIRM 30 JUNE 1977.  
ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING RECALL SHOULD  
BE DIRECTED TO FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

COMESA K.G. PAUL LOUIS  
POSTFACH 75 DIVISION OF AHS/BELGIUM  
VIENNA IX, AUSTRIA 30, CHAUSSEE DE ZELLIK  
B-1080 BRUSSELS  
BELGIUM

AHS/France EDWARDS LABS  
BOITE POSTALE 716 ABT DER MERZ-DADE GMBH  
95004 CERGY 8000 LERCHENSTRASSE 5  
France MUNICH 50, GERMANY

A. PSIMITIS COMPANY NEW DELHI INSTITUTE  
7 MONIS PETRAKI STR. OF MEDICAL SCIENCES  
ATHENS, 140, GREECE DEPT. OF CARDIOLOGY

SEDA, S.A.S.                    AHS  
VIA CARLO RAVIZZA           NO. 4, KAMKAR STREET  
34/1                               MAIDAN SANAI  
20149 MILANO, ITALY        TEHRAN 15, IRAN

AHS/JAPAN                    AHS/PHILIPPINES  
SANDAIDO BUILDING           P.O. BOX 7082  
9-13 AKASAKA 1-CHOME       AIRMAIL EXCHANGE OFFICE  
MINATO-KU                    MANILA INTERNATIONAL A/P  
TOKYO, 107, JAPAN           MANILA, PHILIPPINES 3120

SOC. COM. MULTIRADIX       MEDICAL & SCIENTIFIC CO.  
S.A.R.L.                        32 WATTEN RISE  
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PAGE 04        STATE 196957

P.O. BOX 1970                SINGAPORE 11  
LISBON 1, PORTUGAL        SINGAPORE

DADE-GRIFOLS S.A.           EL MOVIMIENTO  
JESUS Y MARIA 6            VAN'T HOGERHUYSSSTRAAT  
BARCELONA 6                NO. 120  
SPAIN                        PARIMARIBO, SURINAME  
                                  S.A.

VANCE

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NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01-Jan-1994 12:00:00 am  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** RECALLS, FOOD & DRUG REGULATIONS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Sent Date:** 18-Aug-1977 12:00:00 am  
**Decaption Date:** 01-Jan-1960 12:00:00 am  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01-Jan-1960 12:00:00 am  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1977STATE196957  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M.D.:PFF  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D770299-0314  
**Format:** TEL  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1977/newtext/t19770847/aaaabnlq.tel  
**Line Count:** 146  
**Litigation Code IDs:**  
**Litigation Codes:**  
**Litigation History:**  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Message ID:** 13f58a58-c288-dd11-92da-001cc4696bcc  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 3  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Retention:** 0  
**Review Action:** RELEASED, APPROVED  
**Review Content Flags:**  
**Review Date:** 06-Jan-2005 12:00:00 am  
**Review Event:**  
**Review Exemptions:** n/a  
**Review Media Identifier:**  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 1557186  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** CT.; PREM TUR BAXTERY DEPLETION CARDIAC PACEMAKERS (RECALL T-137/138-71)  
**TAGS:** OGEN, ETRD, EIND, TBIO, AU, BE, FR, GE, GR, IN  
**To:** VIENNA BRUSSELS MULTIPLE  
**Type:** TE  
**vdkgvwkey:** odb://SAS/SAS.dbo.SAS\_Docs/13f58a58-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
22 May 2009  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009